Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The pilot study of efficacy of topical formulation of Henna (Lawsonia inermis)1% in itching sensation and wound healing in patients with epidermolysis bullosa: a non randomized open clinical trial

Protocol summary

Study aim
Efficacy of Topical Henna Product in Wound Healing and Pruritus in Patients with Epidermalolysis Bullosa

Design
The clinical trial is without control group and without randomization. The outcome of treatment is evaluated by a physician independent of the study. Patients are evaluated every week for one month.

Settings and conduct
Patients entering the study are selected from patients with Epidermolysis bullosa referred to Molecular Dermatology Research Center. The drug is delivered to the patient in 50-gram containers.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Patients with Epidermolysis Bullosa; 2. Age over 5 years old; 3. Patient or his/her parent's consent to participate in the study**** Exclusion criteria: 1. Patients younger than 5 years old; 2. Patients or their parents not consenting to participate in the study; 3. Positive history of allergic to Henna; 4. Patients with G6PD deficiency (Glucose-6-phosphate dehydrogenase deficiency)

Intervention groups
Intervention group includes patients older than 5 years with Epidermolysis Bullosa who received topical product containing 1% henna extract. is that the patient uses 0.5 grams of cream (equivalent to one finger) twice a day in the itchy area and once a day in the wound area

Main outcome variables
Score of itching and wound healing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150825023753N14**
Registration date: **2019-08-31, 1398/06/09**
Registration timing: **retrospective**

Last update: **2019-08-31, 1398/06/09**
Update count: **0**

Registration date
2019-08-31, 1398/06/09

Registrant information

Name
Mohammad Mahdi Parvizi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 71 3212 5592
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parvizim@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-09-23, 1397/07/01

Expected recruitment end date
2019-01-20, 1397/10/30

Actual recruitment start date
2018-09-23, 1397/07/01

Actual recruitment end date
2018-12-21, 1397/09/30

Trial completion date
2019-05-05, 1398/02/15

Scientific title
The pilot study of efficacy of topical formulation of Henna (Lawsonia inermis)1% in itching sensation and wound healing in patients with epidermolysis bullosa: a non randomized open clinical trial

Public title
Efficacy of topical formulation of Henna in itching sensation and wound healing in patients with epidermolysis bullosa
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with Epidermolysis Bullosa Age over 5 years old Patient or his/her parent's consent to participate in the study
Exclusion criteria:
Patients younger than 5 years old Patients or their parents not consenting to participate in the study Positive history of allergic to Henna Patients with G6PD deficiency (Glucose-6-phosphate dehydrogenase deficiency)
Age
From **5 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **7**
Actual sample size reached: **7**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features
Pilot study, without blinding and randomization

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Shiraz University of Medical Sciences, Zand blv., Shiraz, Fars, Iran
City
Shiraz
Province
Fars
Postal code
7134814336
Approval date
2019-08-14, 1398/05/23
Ethics committee reference number
IR.SUMS.REC.1398.761

Health conditions studied

1

Description of health condition studied
Epidermolysis Bullosa Dystrophica
ICD-10 code
Q81.2
ICD-10 code description
Epidermolysis bullosa dystrophica

Primary outcomes

1

Description
Itching score
Timepoint
Once a week until 1 month
Method of measurement
Visual Analogue Scale (VAS)

2

Description
Percentage of wound healing
Timepoint
Percentage of wound healing
Method of measurement
Clinical global impression of improvement

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group includes patients older than 5 years with Epidermolysis Bullosa who received topical product containing 1% henna extract. is that the patient uses 0.5 grams of cream (equivalent to one finger) twice a day in the itchy area and once a day in the wound area
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Molecular Dermatology Research Center
Full name of responsible person

Dr. Mohammad Mahdi Parvizi
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Shahid Faghihi Hospital, Zand Avenue
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7134846114
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mmparvizi@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Younes Ghasemi
Street address
7th floor,Vice Chancellor of Research, Shiraz University of Medical Sciences, Zand Blvd., Shiraz, Iran
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vcrdep@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Mohammad Mahdi Parvizi
Position
Assistant professor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Demographic data and the results of the clinical trial
When the data will become available and for how long
6 month later
To whom data/document is available
Researchers
Under which criteria data/document could be used
After publication of the extracted article of the clinical trial
From where data/document is obtainable
Sending Email to the researchers
What processes are involved for a request to access data/document
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Comments